

# Exhibit 5

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO FORM 8-K  
ON  
FORM 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): JANUARY 2, 2001

ORGANOGENESIS, INC.  
(Exact name of registrant as specified in its charter)

DELAWARE	1-9898	04-2871690
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

150 DAN ROAD, CANTON, MA 02021  
(Address of principal executive offices) (ZipCode)

Registrant's telephone number, including area code: (781) 575-0775

The sole purpose of this amendment is to add two exhibits to the current Report on Form 8-K filed by Organogenesis, Inc. on March 8, 2001.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

- \* 10.1 Amendment V as of January 2, 2001 to the License and Supply Agreement, by and between Organogenesis, Inc. and Novartis Pharma AG., formerly Sandoz Pharma Ltd.
- \* 10.2 Securities Purchase Agreement, dated February 23, 2001 by and between Organogenesis, Inc. and Novartis Pharma AG., formerly Sandoz Pharma Ltd.
- \*\*99.1 The Registrant's Press Release dated February 8, 2001 entitled "HCFA Establishes National Level of Reimbursement for Apligraf Applied in a Doctor's Office."
- \*\*99.2 The Registrant's Press Release dated February 26, 2001 entitled "Organogenesis Inc. and Novartis Pharma AG Broaden Relationship in the Field of Living Wound-Healing Products."
- \* Confidential treatment requested as to certain portions of the document, which portions have been omitted and filed separately with the Securities and Exchange Commission.

\*\* Previously filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to Form 8-K on Form 8-K/A to be signed on its behalf by the undersigned hereunto duly authorized.

ORGANOGENESIS

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(Registrant)

Date: April 24, 2001

By: /s/ John J. Arcari

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Name: John J. Arcari  
Title: Vice President, Finance and  
Administration, Chief Financial  
Principal financial and Accounting  
Officer

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Exhibit 10.1

AMENDMENT V TO LICENSE AND SUPPLY AGREEMENT

This AMENDMENT V TO THE LICENSE AND SUPPLY AGREEMENT (this "Amendment"), dated as of January 2, 2001, by and between Organogenesis Inc., a company organized under the laws of the State of Delaware with its principal place of business located at 150 Dan Road, Canton, Massachusetts 02021, U.S.A. ("Organogenesis"), and Novartis Pharma AG (formerly Sandoz Pharma Ltd.), a corporation organized under the laws of Switzerland with its principal place of business located at Lichtstrasse 35, CH - 4002 Basel, Switzerland ("Novartis").

Capitalized terms used herein that are not otherwise defined shall have the meanings ascribed to them in the License and Supply Agreement, dated as of January 17, 1996 (the "LSA"), by and between Organogenesis and Novartis.

WHEREAS, pursuant to the LSA, Organogenesis has granted Novartis, among other things, an exclusive license under the Product Patent Rights and Product Technical Information to use, import, sell and offer to sell Product in all countries in the world as further set forth in Schedule A of the LSA; and

WHEREAS, the parties executed amendments to the LSA as follows: (a) Amendment to the License and Supply Agreement, dated January 22/February 4, 1998 (the "First Amendment"); (b) Addendum to the License and Supply Agreement, dated March 23, 1998; (c) Addendum II to the License and Supply Agreement, dated September 4, 1998 (the "Third Amendment"); and (d) Addendum, dated March 15, 2000, to the License and Supply Agreement (the "Fourth Amendment") (collectively, with the LSA and this Amendment, the "Amended LSA"); and

WHEREAS, Novartis agreed, under the Amended LSA to make certain payments to Organogenesis including funding for research and development and royalty payments in exchange for the exclusive license; and

WHEREAS, Novartis wishes to obtain from Organogenesis, and Organogenesis wishes to grant to Novartis, the right to purchase exclusive options to license exclusively from Organogenesis certain rights with respect to Vitrix(TM) (as hereinafter defined) and Vercutis Matrix(TM) (as hereinafter defined), without prejudicing Novartis' or Organogenesis' legal position as to their respective rights to Vitrix and Vercutis Matrix under the LSA as heretofore amended; and

WHEREAS, Novartis and Organogenesis wish to further amend the LSA to include, among other things, enhanced payments for Product under Article 6.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, the parties hereby agree as follows:

1. Article 1 of the Amended LSA is hereby amended to include the following additional definitions:

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"Amended Contract Year" means the one (1) year period commencing on the  
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Effective Date of this Amendment and each succeeding one (1) year period  
thereafter.

"Drawdown Account" shall have the meaning set forth in Article 12.6.  
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"Effective Date of this Amendment" means January 2, 2001.  
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"Field of Use" means all uses except (a) implantation below the surface of  
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the skin (unless such implantation has the primary purpose of repair,  
bulking, filling, replacement, reconstruction or cosmetic or functional  
improvement of the skin, including the immediately underlying soft tissue  
and including skin wounds which extend to the bone), and (b) all  
applications of genetic modifications and drug delivery (unless primarily  
intended for use in connection with repair, bulking, filling, replacement,  
reconstruction or cosmetic or functional improvement of the skin, including  
the immediately underlying soft tissue and including skin wounds which  
extend to the bone).

"GAAP" means generally accepted accounting principles in the U.S. in effect  
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from time to time.

"Performance Measures" means the conditions set forth in Schedule B  
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attached hereto.

"Option Period" shall have the meaning set forth in Article 3.1.1.  
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"Product Development Payment" shall have the meaning set forth in Article  
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4.10.

"Product Payment" shall have the meaning set forth in Article 6.1.  
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"Product Patent Rights" means Patent Rights with respect to Product.  
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"Product Technical Information" means Technical Information with respect to  
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Product.

"Vitrix" or "Vitrix(TM)" means a single layer, living, dermal matrix  
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principally composed of normal allogeneic human dermal fibroblasts and  
bovine Type I collagen, whereby the fibroblasts compact the bovine Type I  
collagen gel and produce human matrix proteins during manufacture.

"Vitrix Consideration" shall have the meaning set forth in Article 3.1.2.  
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"Vitrix Patent Rights" means Patent Rights with respect to Vitrix.  
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"Vitrix Technical Information" means Technical Information with respect to  
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Vitrix.

"Vercutis Matrix" or "Vercutis Matrix(TM) \*\*\*  
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"Vercutis Matrix Consideration" shall have the meaning set forth in Article  
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3.2.2.

"Vercutis Matrix Patent Rights" means Patent Rights with respect to  
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Vercutis Matrix.

"Vercutis Matrix Technical Information" means Technical Information with  
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respect to Vercutis Matrix.

2. Article 1 of the Amended LSA is hereby further amended as follows:

(a) Article 1.11 is hereby deleted in its entirety and replaced with the following:

"Net Sales" means the gross invoice price of the Product  
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sold to independent third party customers in bona fide, arms  
length transactions, less (a) quantity and/or cash discounts  
actually allowed or taken; (b) freight postage and insurance  
(allocated in accordance with Novartis' standard allocation  
procedure, which is in accordance with GAAP); (c) amounts  
repaid or credited by reasons of rejections or return of  
goods or because of retroactive price reductions  
specifically identifiable to Product; (d) amounts payable  
resulting from governmental (or agency thereof) mandated  
rebate programs; (e) third party rebates to the extent  
actually allowed; (f) custom duties and taxes (excluding  
income, value-added and similar taxes), if any, directly  
related to the sale; and (g) any other specifically  
identifiable amounts included in Product's gross sales that  
will be credited for reasons substantially equivalent to  
those listed hereinabove.

(b) Article 1.12 is hereby deleted in its entirety and replaced with the following:

"Patent Rights", with respect to Product, means the patents  
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and patent applications relating to Product set forth in  
Schedule B of the LSA, any divisions, continuations,  
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continuations-in-part, reissues, re-examinations,  
extensions, supplemental protection certificates or other  
governmental actions which extend the subject matter or the  
term of such patent applications or patents, and any  
confirmations, registrations or re-validations of any of the  
foregoing in any additional countries. "Patent Rights", with  
respect to Vitrix means the patents and patent applications  
relating to Vitrix set forth in Schedule A1 and, with  
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respect to Vercutis Matrix, means the patents and patent  
applications relating to Vercutis Matrix set forth in  
Schedule A2, respectively, of this Amendment, and, in each  
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case, any divisions, continuations, continuations-in-part,  
reissues, re-examinations, extensions, supplemental  
protection certificates or other governmental actions which  
extend the subject matter or the term of such respective  
patent applications or patents, and any confirmations,  
registrations

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or re-validations of any of the foregoing in any additional countries.

- (c) Article 1.17 is hereby deleted in its entirety and replaced with the following:

"Technical Information" shall mean, with respect to Product,  
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or with respect to Vitrix or Vercutis Matrix, respectively, any or all results and technical information, including preclinical, manufacturing, clinical or regulatory information relating to Product or Vitrix or Vercutis Matrix that is (i) owned or controlled by Organogenesis on the Effective Date with respect to Product, or on the Vitrix Option Notice Date with respect to Vitrix, or on the Vercutis Matrix Option Notice Date with respect to Vercutis Matrix, as the case may be; and (ii) thereafter developed or acquired by Organogenesis or Novartis during the term hereof.

3. Without limitation to Section 20 of this Amendment, the parties hereby expressly reaffirm the right to sublicense granted to Novartis under Article 2.1 of the Amended LSA.

4. The following shall be inserted as Article 2.4:

2.4 Right of First Refusal for Sublicenses. In the event

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Novartis seeks to enter into an agreement to sublicense to any non-Affiliate third party any of the rights under the Product Patent Rights or Product Technical Information granted to Novartis hereunder, Novartis shall offer in writing to Organogenesis (the "Sublicense Offer") the right

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to match the terms and conditions of the sublicense proposed to be entered into with such non-Affiliate third party (the "Proposed Sublicense"). The Sublicense Offer shall include a

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copy of the letter of intent or equivalent document executed by Novartis and the applicable non-Affiliate third party setting forth a summary of the material terms of the Proposed Sublicense. In the event Organogenesis (a) declines the Sublicense Offer or (b) fails to accept the Sublicense Offer within thirty (30) days after Organogenesis' receipt thereof, in the cases of either (a) or (b), the Sublicense Offer shall terminate and Novartis shall be permitted to enter into a sublicense agreement with the applicable non-Affiliate third party on terms and conditions which, taken as a whole, are no more favorable to such non-Affiliate third party than those contained in the Sublicense Offer.

5. The following shall be inserted as Article 2.5:

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2.5 Technical Information: Organogenesis shall disclose to

Novartis the Product Technical Information within thirty (30) days of the Effective Date. Organogenesis and Novartis shall further disclose to one another all Product Technical Information hereafter developed or acquired by either party during the term of this Agreement. The parties shall also disclose to one another reimbursement studies, market research and manufacture and distribution plans developed or acquired by either party with respect to Product prior to the Effective Date or during the term of this Agreement. Organogenesis warrants that preclinical testing, including safety testing, within the Product Technical Information has been carried out according to Good Laboratory Practice, and that clinical testing within the Product Technical Information has been carried out according to Good Clinical Practice. If Novartis purchases the Vitrix Option or the Vercutis Matrix Option, as the case may be: (a) Organogenesis shall disclose to Novartis the Vitrix Technical Information and/or the Vercutis Matrix Technical Information, as applicable, within thirty (30) days of the respective Vitrix Option Notice Date or the Vercutis Matrix Option Notice Date; and (b) Organogenesis and Novartis shall further disclose to one another all Vitrix Technical Information or Vercutis Matrix Technical Information developed or acquired by either party from and after the applicable Vitrix Option Notice Date or Vercutis Matrix Option Notice Date through the expiration of the applicable Vitrix Option Period (or Vitrix Option Extension Period, if applicable) or Vercutis Matrix Option Period (or Vercutis Matrix Option Extension Period, if applicable); and (c) Organogenesis shall warrant to Novartis, as of the Vitrix Option Notice Date or Vercutis Matrix Option Notice Date, as the case may be, that the preclinical testing, including safety testing, within the Vitrix Technical Information or Vercutis Matrix Technical Information, as the case may be, required to be disclosed to Novartis pursuant to clauses (a) and (b) above has been carried out according to Good Laboratory Practice, and that clinical testing within the Vitrix Technical Information or Vercutis Matrix Technical Information, as the case may be, required to be disclosed to Novartis pursuant to said clauses (a) and (b) has been carried out according to Good Clinical Practice.

6. Article 3 of the Amended LSA is deleted in its entirety and is replaced with the following:

ARTICLE 3. OPTIONS FOR VITRIX AND VERCUTIS MATRIX

3.1 Vitrix Option.

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3.1.1 Right to Purchase Vitrix Option. During the period commencing on the Effective Date of this Amendment and continuing up to and including \*\*\* (the "Purchase Period"), Novartis shall have the right to purchase from Organogenesis, and, upon exercise of such right by Novartis by providing written notice thereof to Organogenesis, Organogenesis shall grant to Novartis, upon the terms and subject to the conditions set forth herein, an option (the "Vitrix Option") to negotiate with Organogenesis for an exclusive license, within the Field of Use, of Vitrix under the Vitrix Patent Rights and Vitrix Technical Information (the "Vitrix License"). The exercise of the Vitrix Option and the scope, terms and conditions of any such Vitrix License shall be subject to negotiation by the parties in accordance with Article 3.1.3. Notwithstanding anything contained herein to the contrary, neither Organogenesis nor any Affiliate thereof shall, during the Purchase Period and, if and only if Novartis timely exercises its right to purchase the Vitrix Option, prior to the expiration of the \*\*\* period (the "Vitrix Option Period") commencing on the date Organogenesis receives from Novartis written notice of Novartis' election to purchase the Vitrix Option (the "Vitrix Option Notice Date"), (a) enter into any agreement with any third party with respect to a license of Vitrix within the Field of Use under any of the Vitrix Patent Rights or Vitrix Technical Information (other than any grant of rights under the Vitrix Patent Rights or Vitrix Technical Information by Organogenesis to any such third party solely for research and development, clinical trials or other non-commercial purposes), or (b) engage, directly or indirectly, in the sale or marketing of Vitrix within the Field of Use; provided, that in no event shall Organogenesis initiate, continue or otherwise engage in any discussions or negotiations with respect to a license of Vitrix within the Field of Use under the Vitrix Patent Rights or Vitrix Technical Information during the \*\*\* day period prior to the expiration of the Vitrix Option Period or any applicable Vitrix Option Extension Period (as hereinafter defined).

3.1.2 Vitrix Consideration. In the event Novartis elects to purchase the Vitrix Option, Novartis shall pay to Organogenesis, as full consideration for the Vitrix Option, an amount equal to \*\*\* of the Vitrix Costs (as hereinafter defined) incurred during the period commencing on the Effective Date of this Amendment and continuing up to and including the date of expiration of the Vitrix Option Period (or, if Novartis exercises its right to extend the Vitrix Option Period, then up to and including the date of the expiration of the Vitrix Option Extension Period), up to \*\*\* (the "Vitrix Consideration"). The "Vitrix Costs" shall mean the research and development and clinical trial costs incurred in good

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faith by Organogenesis with respect to Vitrix (other than costs relating solely to applications of Vitrix outside of the Field of Use), based on schedules to be prepared by Organogenesis in accordance with GAAP and certified by Organogenesis' Chief Financial Officer as having been prepared in good faith. With respect to the period commencing on the Vitrix Option Notice Date and ending on the last day of the calendar quarter in which the Vitrix Option Notice Date falls and with respect to each succeeding calendar quarter until the expiration of the Vitrix Option Period (or, if Novartis exercises its right to extend the Vitrix Option Period, then up to and including the date of expiration of the Vitrix Option Extension Period), Organogenesis shall submit to Novartis on a quarterly basis and within thirty (30) days after the end of each such quarter (each, a "Vitrix Submission Period") such invoices,

receipts and other written documentation reasonably requested by Novartis (and which is in Organogenesis' possession or Organogenesis can obtain without unreasonable effort or expense), including without limitation the schedules referred to above (collectively, the "Vitrix

Documentation"), setting forth in reasonable detail the

Vitrix Costs incurred during such just-ended Vitrix Submission Period (or, with respect to the first such Vitrix Submission Period, such Vitrix Costs incurred during the period from the Effective Date of this Amendment up to the expiration of such first Vitrix Submission Period). Novartis shall pay to Organogenesis an amount equal to such Vitrix Costs within thirty (30) days after Novartis' receipt of the Vitrix Documentation corresponding to each Vitrix Submission Period.

### 3.1.3 Negotiation of Vitrix License. Commencing

\*\*\*, Novartis may exercise the Vitrix Option by providing written notice thereof to Organogenesis. Promptly thereafter, the parties shall negotiate in good faith and on an exclusive basis to enter into a Vitrix License, the terms of which may include any one or more of a license fee, guaranteed minimum payments and/or a percentage split of sales, as well as such other terms and conditions of a license agreement as the parties may agree; provided, that a failure of the parties to execute and deliver a license agreement for Vitrix shall not in and of itself constitute a failure to negotiate in good faith. In the event the parties are unable to execute and deliver a license agreement for Vitrix (a "Vitrix License Agreement") prior to the

expiration of the Vitrix Option Period, Novartis may, by providing written notice thereof to Organogenesis prior to such expiration, extend the Vitrix Option Period at no additional cost for an additional \*\*\* days after such expiration or until the parties execute and deliver a Vitrix License Agreement, whichever occurs first (the "Vitrix

Option Extension

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Period"). In the event the parties are unable to execute and deliver a Vitrix License Agreement prior to the expiration of the Vitrix Option Extension Period, the Vitrix Option shall terminate and Organogenesis may thereafter negotiate and enter into an agreement to license rights to Vitrix under the Vitrix Patent Rights and Vitrix Technical Information to one or more third parties. If, following the termination of the Vitrix Option, Organogenesis seeks to enter into such an agreement with respect to a license of Vitrix within the Field of Use with one or more third parties during the term of this Agreement, Organogenesis shall offer in writing to Novartis the right to match the terms of the Vitrix License Agreement proposed to be entered into with each such third party (the "Third Party Vitrix Offer"). Such offer to Novartis shall include a copy of the letter of intent or equivalent document executed by Organogenesis and the applicable third party setting forth a summary of the material terms of the Third Party Vitrix Offer (the "Vitrix Letter of Intent"). In the event Novartis declines such offer or otherwise fails to accept such offer within sixty (60) days after Novartis' receipt thereof (in each case, a "Vitrix Non-Acceptance"), Organogenesis shall be permitted to enter into a license agreement for Vitrix with the applicable third party in accordance with the terms and conditions of the Third Party Vitrix Offer. In the event of a Vitrix Non-Acceptance, if the terms and conditions of the final license agreement for Vitrix between Organogenesis and the applicable third party are amended or otherwise altered so that they differ materially from those set forth in the Vitrix Letter of Intent, prior to executing and delivering such final license agreement Organogenesis shall offer to Novartis in writing the right to license Vitrix on the same terms and conditions as set forth in such final license agreement. In the event Novartis declines such offer or otherwise fails to accept such offer within ten (10) days after Novartis' receipt thereof, Organogenesis shall be permitted to execute and deliver such final license agreement.

#### 3.1.4 Right to Reimbursement. Without limitation to

Novartis' rights under Article 3.1.3, in the event the parties do not execute and deliver a Vitrix License Agreement pursuant to Article 3.1.3, Organogenesis shall return to Novartis (a) \*\*\* if, during the \*\*\* period commencing on the day after expiration of the Vitrix Option Period or applicable Vitrix Option Extension Period, Organogenesis or an Affiliate thereof directly sells or markets Vitrix commercially within the Field of Use anywhere in the Territory; or (b) \*\*\* if, during the \*\*\* period commencing on the day after expiration of the Vitrix Option Period or applicable Vitrix Option Extension Period, Organogenesis enters into one or more license agreements for Vitrix within the Field of Use with any third

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party or parties (other than any license solely for research and development, clinical trials or other non-commercial purposes); provided, however, that (x) in the event

Organogenesis is required to return to Novartis \*\*\* under clause (b) above subsequent to Organogenesis having been required to return to Novartis the amount required under clause (a) above (and having actually made the entirety of such payment), Organogenesis shall only be required to return to Novartis \*\*\*, and (y) in no event shall Organogenesis be required under this Article 3.1.4 to return to Novartis an aggregate of more than \*\*\*. Organogenesis shall pay to Novartis any amounts required to be paid by Organogenesis under this Article 3.1.4 on or before thirty (30) days after the date of the relevant sale or marketing of Vitrix under clause (a) above (the "Vitrix Sale/Marketing Date") or on or

before \*\*\* days after the effective date of the first such license agreement for Vitrix under clause (b) above. Notwithstanding the foregoing, Organogenesis may pay to Novartis any amount required to be paid by Organogenesis with respect to clause (a) above subsequent to the expiration of \*\*\* days after the Vitrix Sale/Marketing Date, but in any event shall pay all such amounts prior to the expiration of \*\*\* days after the Vitrix Sale/Marketing Date \*\*\*.

### 3.2 Vercutis Matrix Option.

#### 3.2.1 Right to Purchase Vercutis Matrix Option.

During the Purchase Period, Novartis shall have the right to purchase from Organogenesis, and, upon exercise of such right by Novartis by providing written notice thereof to Organogenesis, Organogenesis shall grant to Novartis, upon the terms and subject to the conditions set forth herein, an option (the "Vercutis Matrix Option") to negotiate with

Organogenesis for an exclusive license, within the Field of Use, of Vercutis Matrix under the Vercutis Matrix Patent Rights and Vercutis Matrix Technical Information (the "Vercutis Matrix License"). The exercise of the Vercutis

Matrix Option and the scope, terms and conditions of any such Vercutis Matrix License shall be subject to negotiation by the parties in accordance with Article 3.2.3.

Notwithstanding anything contained herein to the contrary, neither Organogenesis nor any Affiliate thereof shall, during the Purchase Period and, if and only if Novartis timely exercises its right to purchase the Vercutis Matrix Option, prior to the expiration of the \*\*\* period (the "Vercutis Matrix Option Period") commencing on the date

Organogenesis receives from Novartis written notice of Novartis' election to purchase the Vercutis Matrix Option (the "Vercutis Matrix Option Notice Date"), (a) enter into

any agreement with any third party with respect to a license of Vercutis Matrix within

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the Field of Use under any of the Vercutis Matrix Patent Rights or Vercutis Matrix Technical Information (other than any grant of rights under the Vercutis Matrix Patent Rights or Vercutis Matrix Technical Information by Organogenesis to any such third party solely for research and development, clinical trials or other non-commercial purposes), or (b) engage, directly or indirectly, in the sale or marketing of Vercutis Matrix within the Field of Use; provided, that in

no event shall Organogenesis initiate, continue or otherwise engage in any discussions or negotiations with respect to a license of Vercutis Matrix within the Field of Use under the Vercutis Matrix Patent Rights or Vercutis Matrix Technical Information during the \*\*\* day period prior to the expiration of the Vercutis Matrix Option Period or any applicable Vercutis Matrix Option Extension Period (as hereinafter defined).

3.2.2 Vercutis Matrix Consideration. In the event

Novartis elects to purchase the Vercutis Matrix Option, Novartis shall pay to Organogenesis, as full consideration for the Vercutis Matrix Option, an amount equal to \*\*\* of the Vercutis Matrix Costs (as hereinafter defined) incurred during the period commencing on the Effective Date of this Amendment and continuing up to and including the date of expiration of the Vercutis Matrix Option Period (or, if Novartis exercises its right to extend the Vercutis Matrix Option Period, then up to and including the date of the expiration of the Vercutis Matrix Option Extension Period), up to \*\*\* (the "Vercutis Matrix Consideration"). In the

event Organogenesis receives from the FDA or the CPMP, within \*\*\* after the Vercutis Matrix Option Notice Date, PMA Approval for any indications within the Field of Use sought by Organogenesis with respect to Vercutis Matrix (the "Vercutis Matrix Approval"), the maximum amount payable by

Novartis to Organogenesis as Vercutis Matrix Consideration shall be increased to \*\*\* (the "Increased Maximum") and,

subject to the Increased Maximum, Novartis shall be responsible for \*\*\* of the Vercutis Matrix Costs. The "Vercutis Matrix Costs" shall mean the research and

development and clinical trial costs incurred in good faith by Organogenesis with respect to Vercutis Matrix (other than costs relating solely to applications of Vercutis Matrix outside of the Field of Use), based on schedules to be prepared by Organogenesis in accordance with GAAP and certified by Organogenesis' Chief Financial Officer as having been prepared in good faith. With respect to the period commencing on the Vercutis Matrix Option Notice Date and ending on the last day of the calendar quarter in which the Vercutis Matrix Option Notice Date falls and with respect to each succeeding calendar quarter until the expiration of the Vercutis Matrix Option Period (or, if Novartis

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exercises its right to extend the Vercutis Matrix Option Period, then up to and including the date of expiration of the Vercutis Matrix Option Extension Period), Organogenesis shall submit to Novartis on a quarterly basis and within thirty (30) days after the end of each such quarter (each, a "Vercutis Matrix

Submission Period") such invoices, receipts and other written documentation reasonably requested by Novartis (and which is in Organogenesis' possession or Organogenesis can obtain without unreasonable effort or expense), including without limitation the schedules referred to above (collectively, the "Vercutis Matrix

Documentation"), setting forth in reasonable detail the

Vercutis Matrix Costs incurred during such just-ended Vercutis Matrix Submission Period (or, with respect to the first such Vercutis Matrix Submission Period, such Vercutis Matrix Costs incurred during the period from the Effective Date of this Amendment up to the expiration of such first Vercutis Matrix Submission Period). Novartis shall pay to Organogenesis an amount equal to such Vercutis Matrix Costs within thirty (30) days after Novartis' receipt of the Vercutis Matrix Documentation corresponding to each Vercutis Matrix Submission Period. In addition, if Organogenesis receives Vercutis Matrix Approval, Novartis shall pay to Organogenesis, within thirty (30) days after receipt of notice thereof from Organogenesis, an amount equal to \*\*\*.

### 3.2.3 Negotiation of Vercutis Matrix License.

Commencing \*\*\*, Novartis may exercise the Vercutis Matrix Option by providing written notice thereof to Organogenesis. Promptly thereafter, the parties shall negotiate in good faith and on an exclusive basis to enter into a Vercutis Matrix License, the terms of which may include any one or more of a license fee, guaranteed minimum payments and/or a percentage split of sales, as well as such other terms and conditions of a license agreement as the parties may agree; provided, that a failure of the parties to execute and deliver a license agreement for Vercutis Matrix shall not in and of itself constitute a failure to negotiate in good faith. In the event the parties are unable to execute and deliver a license agreement for Vercutis Matrix (a "Vercutis Matrix License Agreement") prior to the

expiration of the Vercutis Matrix Option Period, Novartis may, by providing written notice thereof to Organogenesis prior to such expiration, extend the Vercutis Matrix Option Period at no additional cost for an additional \*\*\* days after such expiration or until the parties execute and deliver a Vercutis Matrix License Agreement, whichever occurs first (the "Vercutis Matrix Option Extension Period"). In the

event the parties are unable to execute and deliver a Vercutis Matrix License Agreement prior to the expiration of the Vercutis Matrix Option

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Extension Period, the Vercutis Matrix Option shall terminate and Organogenesis may thereafter negotiate and enter into an agreement to license rights to Vercutis Matrix under the Vercutis Matrix Patent Rights and Vercutis Matrix Technical Information to one or more third parties. If, following the termination of the Vercutis Matrix Option, Organogenesis seeks to enter into such an agreement within the Field of Use with one or more third parties during the term of this Agreement, Organogenesis shall offer in writing to Novartis the right to match the terms of the Vercutis Matrix License Agreement proposed to be entered into with each such third party (the "Third Party Vercutis Matrix Offer"). Such offer to Novartis shall include a copy of the letter of intent or equivalent document executed by Organogenesis and the applicable third party setting forth a summary of the material terms of the Third Party Vercutis Matrix Offer (the "Vercutis Matrix Letter of Intent"). In the event Novartis declines such offer or otherwise fails to accept such offer within sixty (60) days after Novartis' receipt thereof (in each case, a "Vercutis Matrix Non-Acceptance"), Organogenesis shall be permitted to enter into a license agreement for Vercutis Matrix with the applicable third party in accordance with the terms and conditions of the Third Party Vercutis Matrix Offer. In the event of a Vercutis Matrix Non-Acceptance, if the terms and conditions of the final license agreement for Vercutis Matrix between Organogenesis and the applicable third party are amended or otherwise altered so that they differ materially from those set forth in the Vercutis Matrix Letter of Intent, prior to executing and delivering such final license agreement Organogenesis shall offer to Novartis in writing the right to license Vercutis Matrix on the same terms and conditions as set forth in such final license agreement. In the event Novartis declines such offer or otherwise fails to accept such offer within ten (10) days after Novartis' receipt thereof, Organogenesis shall be permitted to execute and deliver such final license agreement.

3.2.4 Right to Reimbursement. Without limitation to Novartis' rights under Article 3.2.3, in the event the parties do not execute and deliver a Vercutis Matrix License Agreement pursuant to Article 3.2.3, Organogenesis shall return to Novartis (a) \*\*\* if, during the \*\*\* period commencing on the day after expiration of the Vercutis Matrix Option Period or applicable Vercutis Matrix Option Extension Period, Organogenesis or an Affiliate thereof directly sells or markets Vercutis Matrix commercially within the Field of Use anywhere in the Territory; or (b) \*\*\* if, during the \*\*\* period commencing on the day after expiration of the Vercutis Matrix Option Period or applicable Vercutis Matrix Option Extension Period, Organogenesis enters into one or more license

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agreements for Vercutis Matrix within the Field of Use with any third party or parties (other than any license solely for research and development, clinical trials or other non-commercial purposes); provided, however, that

(x) in the event Organogenesis is required to return to Novartis \*\*\* under clause (b) above subsequent to Organogenesis having been required to return to Novartis the amount required under clause (a) above (and having actually made the entirety of such payment), Organogenesis shall only be required to return to Novartis \*\*\*, and (y) in no event shall Organogenesis be required under this Article 3.2.4 to return to Novartis \*\*\*. Organogenesis shall pay to Novartis any amounts required to be paid by Organogenesis under this Article 3.2.4 on or before \*\*\* days after the date of the relevant sale or marketing of Vercutis Matrix under clause (a) above (the "Vercutis Matrix Sale/Marketing Date") or on or before

thirty (30) days after the effective date of the first such license agreement for Vercutis Matrix under clause (b) above. Notwithstanding the foregoing, Organogenesis may pay to Novartis any amount required to be paid by Organogenesis with respect to clause (a) above subsequent to the expiration of \*\*\* days after the Vercutis Matrix Sale/Marketing Date, but in any event shall pay all such amounts prior to the expiration of \*\*\* days after the Vercutis Matrix Sale/Marketing Date \*\*\*.

7. Article 4 of the Amended LSA is hereby amended as follows:

(a) In the second sentence of Article 4.4, (i) the words "Organogenesis's President" shall be deleted and replaced by "Organogenesis' Chief Executive Officer", and (ii) the words "Sandoz' Head of Business Development" shall be deleted and replaced by "Novartis' Head of Transplant, Tissue Engineering and Immunology Business Unit."

(b) A new Article 4.8.3 shall be inserted as follows:

4.8.3 Product Quality. Organogenesis agrees

that it shall comply with all applicable laws and regulations in connection with the manufacture and packaging of Product, including, without limitation, current Good Manufacturing Practices.

(c) A new Article 4.10 shall be inserted as follows:

4.10 Product Development Payment. Novartis shall

pay to Organogenesis, in accordance with Article 7.1, an amount equal to \*\*\* of the research and development and clinical trial costs incurred in good faith by Organogenesis during the term of this Agreement, based on schedules to be prepared by Organogenesis

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in accordance with GAAP and certified by Organogenesis' Chief Financial Officer as having been prepared in good faith, up to a maximum payment by Novartis of \*\*\* (the "Product Development Payment"), with respect to the

following indications for Product: (a) dermatologic (cosmetic) surgery; (b) decubitis ulcers; (c) burn therapy; (d) cryopreserved Apligraf; and (e) such other indications as are agreed upon unanimously by the JDC or its successor committee. The JDC or such successor committee shall allocate resources and expenditures among such indications; provided, that any expenditures

shall be subject to the unanimous prior consent of the members of the JDC or such successor committee (it being agreed that any such consent by the JDC shall cover the aggregate amount of expenditures covered by such consent and shall not be revoked without the unanimous consent of the JDC). Novartis shall have the right to review and audit all research and development and clinical trials conducted by or on behalf of Organogenesis with respect to such indications for Product.

8. Article 5 of the Amended LSA, including Articles 5.2.1 and 5.2.2 as set forth in the First Amendment and as further revised, with respect to Article 5.2.2, by the Third Amendment, is hereby deleted in its entirety and shall be of no further force or effect; provided, that the heading "ARTICLE 5. [DELIBERATELY LEFT BLANK]" shall be retained for section numbering purposes.
9. Article 6 of the Amended LSA is deleted in its entirety and is replaced with the following:

**ARTICLE 6. PRODUCT PAYMENT**

**6.1 Product Payment. Subject to Article 6.2,**

Novartis shall pay to Organogenesis, in accordance with Article 7.2, an amount (the "Product Payment") equal to

(a) \*\*\* of Net Sales in the Territory by Novartis and its Affiliates and sublicensees with respect to sales during each Amended Contract Year of up to and including \*\*\* units of Product, plus (b) \*\*\* of Net Sales in the Territory by Novartis and its Affiliates and sublicensees with respect to incremental sales, if any, during each such Amended Contract Year \*\*\* units of Product; provided, however, that the percentages in

both clauses (a) and (b) shall be decreased by up to \*\*\* in the event Organogenesis fails to achieve the Performance Measures, in accordance with and as further set forth in Schedule B attached hereto. Organogenesis

shall provide to Novartis, within thirty (30) days after the end of each calendar quarter during the term of the Amended LSA, a reasonably detailed summary of Organogenesis' performance and achievements with respect to the Performance Measures during the corresponding just-ended calendar quarter.

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6.2 Paid-Up License. For each country in the

Territory, following expiration of the last to expire of the Product Patent Rights in each such country or ten (10) years following the First Commercial Sale of Product in that country, whichever is later (the "Expiration Date"), Novartis shall have a perpetual,

non-exclusive, paid-up and royalty-free license, under any remaining know-how or other rights of Organogenesis, to use and sell Product in that country, it being understood that, from and after the Expiration Date with respect to any country, Organogenesis shall not be obligated to supply Novartis with Product for sales in that country unless the parties have executed and delivered a supply agreement setting forth the terms and conditions upon which Organogenesis will supply such Product. After expiration of this Agreement according to Article 16.1, and subject to any Supply Agreement as contemplated in Article 12.1, Novartis shall have a perpetual, non-exclusive, paid-up and royalty-free license, under any remaining know-how or other rights of Organogenesis, to make or have made Product.

6.3 Unsold Units. In addition to the Product

Payments referred to in Article 6.1, Novartis shall pay Organogenesis \*\*\* per unit for each unit of Product ordered by Novartis or its Affiliates or sublicensees but not sold for commercial use (each such unit, an "Unsold Unit"). However, if in any Amended Contract

Year, the number of Unsold Units ordered by Novartis and its Affiliates and sublicensees exceeds the Annual Limit (as defined below), then Novartis shall pay Organogenesis \*\*\* per unit (rather than \*\*\* per unit) for each Unsold Unit in excess of the Annual Limit. As used herein, "Annual Limit", for any Amended Contract

Year, means the greater of (1) \*\*\* units or (2) \*\*\* of the aggregate number of units of Product ordered by Novartis and its Affiliates and sublicensees in such Amended Contract Year for commercial and non-commercial use. For clarification purposes, Unsold Units shall not include units provided at no additional cost and units provided at a rate of \*\*\* per unit in accordance with Article 12.5, but shall include returns of units originally shipped for commercial use other than returns of defective units. Payments for Unsold Units pursuant to this Article 6.3, as well as any payment for units provided for non-commercial use pursuant to Article 12.5, shall be made monthly within thirty (30) days after the end of each applicable month.

10. Article 7 of the Amended LSA is hereby amended as follows:

- (a) Article 7.1 shall be deleted in its entirety and replaced with the following:

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7.1 Product Development Payment. With respect to

the period commencing on the Effective Date of this Amendment and ending on the last day of the calendar quarter in which the Effective Date of this Amendment falls and with respect to each succeeding calendar quarter during the term of the Amended LSA, Organogenesis shall submit to Novartis, on a quarterly basis and within thirty (30) days after the end of each just-ended quarter (each, a "Product Submission

Period"), the invoices, receipts and other written

documentation reasonably requested by Novartis (and which is in Organogenesis' possession or Organogenesis can obtain without unreasonable effort or expense), including without limitation the schedules referred to in Article 4.10, setting forth in reasonable detail Organogenesis' research and development and clinical trial costs approved unanimously by the JDC pursuant to Article 4.10 and incurred in good faith during such just-ended Product Submission Period. Novartis shall pay to Organogenesis the Product Development Payment in amounts equal to such costs within thirty (30) days after the end of each Product Submission Period.

- (b) Article 7.2 shall be deleted in its entirety and replaced with the following:

7.2 Product Payment. With respect to the calendar

month in which the Effective Date of this Amendment falls and with respect to each succeeding calendar month during the term of the Amended LSA, Novartis shall pay to Organogenesis, within \*\*\* days after the end of each such month, the Product Payment with respect to each such month, together with an accounting report showing the quantity of Product sold by Novartis and its Affiliates or sublicensees in the Territory. Novartis may adjust each such monthly payment immediately following a calendar quarter during the term of the Amended LSA to reflect any reductions attributable to the failure by Organogenesis to achieve the applicable Performance Measures for such calendar quarter or any previous calendar quarter (to the extent such adjustment has not already been made) or for any other applicable adjustments to the calculation of Net Sales for any prior sales of Product (and an accounting report showing the calculation of any such deductions and/or adjustments shall accompany such payments(s)).

- (c) Article 7.3 shall be deleted in its entirety and replaced with the following:

7.4 Currency Exchange. The Product Payments provided

to Organogenesis shall be made in U.S. Dollars, and for Product Payments in respect of Net Sales of Product invoiced in currency other than U.S. Dollars, shall be determined on the basis of Novartis' monthly standard account of sales which represents the

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conversion of all local currency sales to Swiss Francs at the average monthly exchange rate of sales. The average exchange rate between the Swiss Franc and U.S. Dollar shall be the rate published in the London Times at the close of business in London on the last ten (10) days of the month for which the Product Payments are being paid.

- (d) Article 7.5 shall be deleted in its entirety and replaced with the following:

7.5 Records and Audit. Each party shall keep accurate records and books of accounts in accordance with GAAP consistently applied and containing all the data reasonably required for calculation and verification of any payments to be made or received hereunder, including, without limitation, with respect to the Vitrix Consideration, the Vercutis Matrix Consideration, the Product Development Payment, the Product Payment and any funds disbursed from the Drawdown Account. During the term of this Agreement and for a period of two (2) years thereafter, each party shall retain accounting records of the previous three (3) years. At the request of either party (an "Auditing Party"), the other party shall make records available, no more than \*\*\* a year, during reasonable working hours for review by an independent accounting firm acceptable to both parties, at the expense of the Auditing Party, for the sole purpose of verifying their accuracy. In the event that any such review indicates an underpayment of the Product Payment or an overpayment of any of the Vitrix Consideration, the Vercutis Matrix Consideration, the Product Development Payment or the funds disbursed from the Drawdown Account (in relation to the use of such funds as set forth in documentation provided by Organogenesis to Novartis in connection with obtaining Novartis' approval of the disbursement thereof) in excess of five percent (5%), the expense of the audit shall be paid by the non-Auditing Party and the non-Auditing Party shall promptly pay to the Auditing Party the amount of such underpayment or return to the Auditing Party the amount of such overpayment.

- (e) Article 7.6 shall be deleted in its entirety and replaced with the following:

7.6 Taxes. All Product Payments required to be paid to Organogenesis pursuant to this Agreement shall be paid with deduction for withholding for or on account of any taxes (other than taxes imposed on or measured by net income) or similar governmental charge imposed by a jurisdiction other than the U.S. ("Withholding Taxes"). Novartis shall provide Organogenesis a certificate evidencing payment of any Withholding Taxes hereunder and provide reasonable assistance to recover such taxes.

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11. Article 12 of the Amended LSA is hereby amended as follows:

(a) Article 12.4 of the Amended LSA is hereby deleted in its entirety and replaced with the following:

12.4 Payment for Product. All payments by Novartis to Organogenesis relating to the supply of Product to Novartis shall be covered under Article 6 or, with respect to non-commercial supply, under Article 12.5.

(b) Article 12.5 of the Amended LSA is hereby deleted in its entirety and replaced with the following:

12.5 Non-Commercial Supply. During each of the first \*\*\* Amended Contract Years commencing on the Effective Date of this Agreement, Organogenesis shall provide Novartis, at no additional cost and as Novartis may request from time to time, an annual supply of \*\*\* units of Product for Novartis' non-commercial use. In the event Novartis requires units of Product for non-commercial use in excess of such annual amount in any of the first \*\*\* Amended Contract Years or any units of Product for non-commercial use at any time subsequent to the first \*\*\* Amended Contract Years, Organogenesis shall provide Novartis with such units of Product at a rate equal to \*\*\* per unit.

(c) A new Article 12.6 shall be inserted as follows:

12.6 Drawdown Account. Promptly after the

Effective Date of this Amendment, Novartis shall make available to Organogenesis an amount of up to \*\*\* (the "Drawdown Account"), in order to facilitate

Organogenesis' performance of its manufacturing obligations and for the benefit of Novartis, (a) to purchase machinery and equipment to upgrade Organogenesis' existing U.S. manufacturing facility and related manufacturing processes in connection with improving the quality of Product manufactured thereby, (b) to develop the European manufacturing suite, (c) to upgrade Organogenesis' manufacturing facilities or construct a new such facility, and (d) to construct laboratories and related premises displaced by the European manufacturing suite. Organogenesis agrees to use commercially practicable efforts to implement such upgrades and pursue such development, provided that Novartis makes the required funds available pursuant to this Article 12.6. In the event Organogenesis seeks any disbursement of funds from the Drawdown Account, Organogenesis shall provide Novartis with written notice thereof, together with schedules to be prepared by Organogenesis in accordance with

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GAAP and certified by Organogenesis' Chief Financial Officer as having been prepared in good faith setting and forth the particulars and details of how such funds shall be used, and any other documentation reasonably requested by Novartis. Any disbursement of funds shall be subject to the prior written consent of Novartis, such consent not to be unreasonably withheld, conditioned or delayed. The parties agree that consent by Novartis pursuant to this Article 12.6 to any upgrade or development project shall cover the disbursement of the aggregate amount of funding to which Novartis has given its consent, whether Organogenesis seeks disbursement of such funding in a single installment or in multiple installments.

12. Article 13 of the Amended LSA is hereby amended as follows:

- (a) The existing text of Article 13 shall be renumbered under the heading: "13.1 Distribution."

- (b) A new Article 13.2 shall be added as follows:

13.2 Direct Billing Costs: In the event Novartis or any Affiliate thereof alters the distribution or billing arrangements for Product, including, without limitation, the establishment and operation of a direct billing operation, in a manner which results in an increase in the per unit sales price invoiced by Novartis or any Affiliate thereof for Product (a "Revised Distribution Arrangement"), Organogenesis shall pay to Novartis an amount equal to \*\*\* of the start-up costs incurred in good faith by Novartis or its applicable Affiliate in connection with such Revised Distribution Arrangement during the period commencing on the Effective Date of this Amendment and ending on \*\*\*, up to \*\*\* of any increase in Net Sales attributable to the Revised Distribution Arrangement (such amount to be paid by Organogenesis to be hereinafter referred to as the "Organogenesis Direct

Billing Costs"). In the event of a Revised Distribution

Arrangement with respect to the period commencing on the Effective Date of this Amendment and ending on the last day of the calendar quarter in which the Effective Date of this Amendment falls and with respect to each succeeding calendar quarter until \*\*\*, Novartis shall submit to Organogenesis on a quarterly basis and within thirty (30) days after the end of each such quarter such invoices, receipts and other documentation reasonably requested by Organogenesis and which is in Novartis' possession or which Novartis can obtain without unreasonable effort or expense (the "Distribution Cost Documentation") setting forth in

reasonable detail the Organogenesis Direct Billing Costs incurred during such just-ended three (3) month period. Organogenesis shall pay to Novartis

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an amount equal to such Organogenesis Direct Billing Costs within \*\*\* days after Organogenesis' receipt of the Distribution Cost Documentation corresponding to each such three (3) month period.

13. Without limitation to Section 20 of this Amendment, the parties hereby expressly reaffirm the confidentiality obligations set forth in Article 15 of the LSA. In addition, the parties hereby agree that neither party shall be permitted to issue any press release or announcement relating to this Amendment without having provided the other party with a copy of the proposed press release or announcement and without the prior written consent of the other party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, the parties agree that Organogenesis may issue the press release attached hereto as Schedule C and that Organogenesis may disclose to third parties the information contained in such press release without the need for further approval by Novartis.
14. Article 16.4 of the Amended LSA and Schedule C thereto are hereby deleted in their entirety and replaced with the following:
- 16.4. Permissive Termination: Novartis may terminate this Agreement upon ninety (90) days written notice in the event it discontinues development of Product for reasons in Novartis' reasonable judgment related to safety or efficacy of the Product, or in the event \*\*\*.
15. Article 18.4 of the Amended LSA is hereby deleted in its entirety and replaced with the following:

18.4 Assignment.

18.4.1 General. This Agreement, including any rights under or relating to this Agreement, shall not be assignable in whole or in part by either party to any third party without the written consent of the other party hereto except that (a) Novartis may assign any or all of its rights and obligations under this Agreement, without the consent of Organogenesis, to a designated Affiliate of Novartis or as provided in Article 18.4.2, and (b) either party may assign all of its rights and obligations under this Agreement to an entity that acquires all or substantially all of the business or assets of such party, whether by merger, reorganization, acquisition, sale or otherwise, without the consent of the other party hereto, provided, however that if Novartis assigns its rights and obligations to an Affiliate pursuant to clause (a) above, any further assignment by such Affiliate to an acquiring entity shall be permitted under clause (b) only if such entity acquires all or substantially all of the business or assets of Novartis and such Affiliate. For purposes of this Article 18, the sale to a non-Affiliate third party of the stock of an Affiliate to which any

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rights or obligations under this Agreement have been assigned shall constitute an assignment of such Affiliate's rights and obligations under this Agreement to such non-Affiliate third party, if the sale of such stock shall cause such Affiliate to cease to be an Affiliate immediately after the effectiveness of such sale. This Agreement shall be binding upon and inure to the benefit of any permitted assignee, and any such assignee shall agree to perform the obligations of the assignor. In the event Novartis assigns its rights under this Agreement, including in accordance with Article 18.4.2: (x) if such assignment includes rights to market and sell Product in the U.S., Novartis shall include as part of the terms and conditions of such assignment the assignment of all of Novartis' right, title and interest in and to U.S. Trademark Reg. No. 2,164,413, including any goodwill symbolized thereby; and (y) if such assignment includes rights to market and sell Product in any country or countries other than the U.S., Novartis shall include as part of the terms and conditions of such assignment, the assignment of all of Novartis' right, title and interest in and to any trademarks used by Novartis solely in connection with the sale of Product in such country or countries and any goodwill symbolized thereby.

18.4.2 Assignment by Novartis. Except as provided in

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clause (b) of Article 18.4.1, Novartis shall not assign any or all of its rights and obligations under this Agreement to a non-Affiliate third party prior to \*\*\*. In the event Novartis seeks to assign any or all of its rights and obligations under this Agreement to a non-Affiliate third party on \*\*\* or at any time thereafter, Novartis shall offer to Organogenesis in writing (the "Organogenesis Offer") the

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right to acquire and assume such rights and obligations \*\*\* (the "Third Party Assignment Offer") \*\*\*. If Organogenesis accepts the

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Organogenesis Offer, Organogenesis shall pay Novartis all of the consideration payable to Novartis in connection therewith in cash; provided, that Organogenesis shall not be required to pay any of such

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consideration prior to the later of (a) sixty (60) days following the date of such acceptance, or (b) the date on which the non-Affiliate third party would have been required to make such payment pursuant to the Third Party Assignment Offer. Notwithstanding the foregoing, in the event the consideration to be paid by such non-Affiliate third party pursuant to the Third Party Assignment Offer includes any non-cash consideration (the "Non-Cash Consideration"), Novartis shall

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determine on a good faith basis the cash value of the Non-Cash Consideration in order to determine the cash consideration to be paid by Organogenesis pursuant to the corresponding Organogenesis Offer. The Organogenesis Offer shall include a